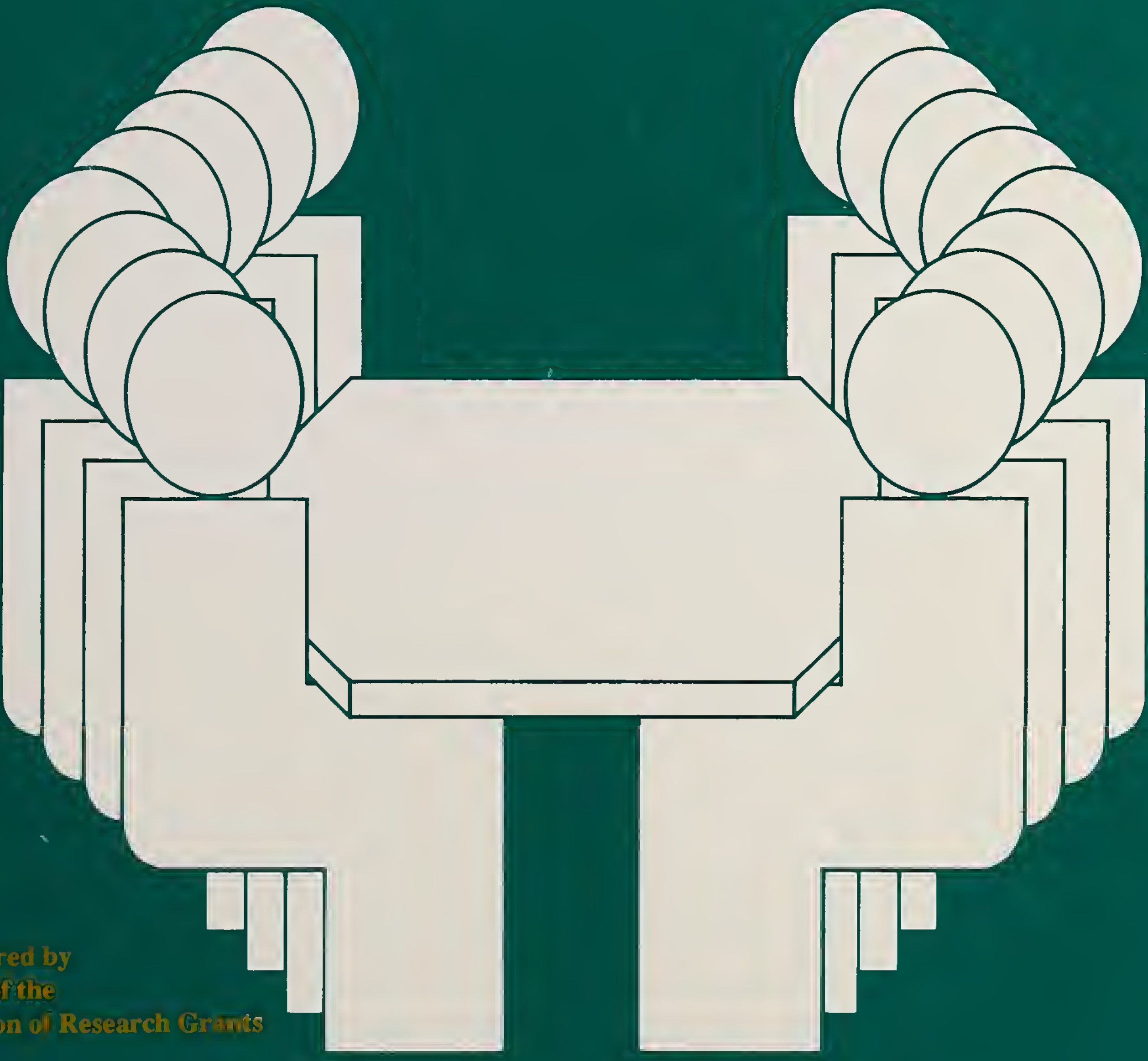
ORIENTATION HANDBOOK FOR MEMBERS OF SCIENTIFIC REVIEW GROUPS

National
Institutes
of Health

June 1989



Prepared by
Staff of the
Division of Research Grants

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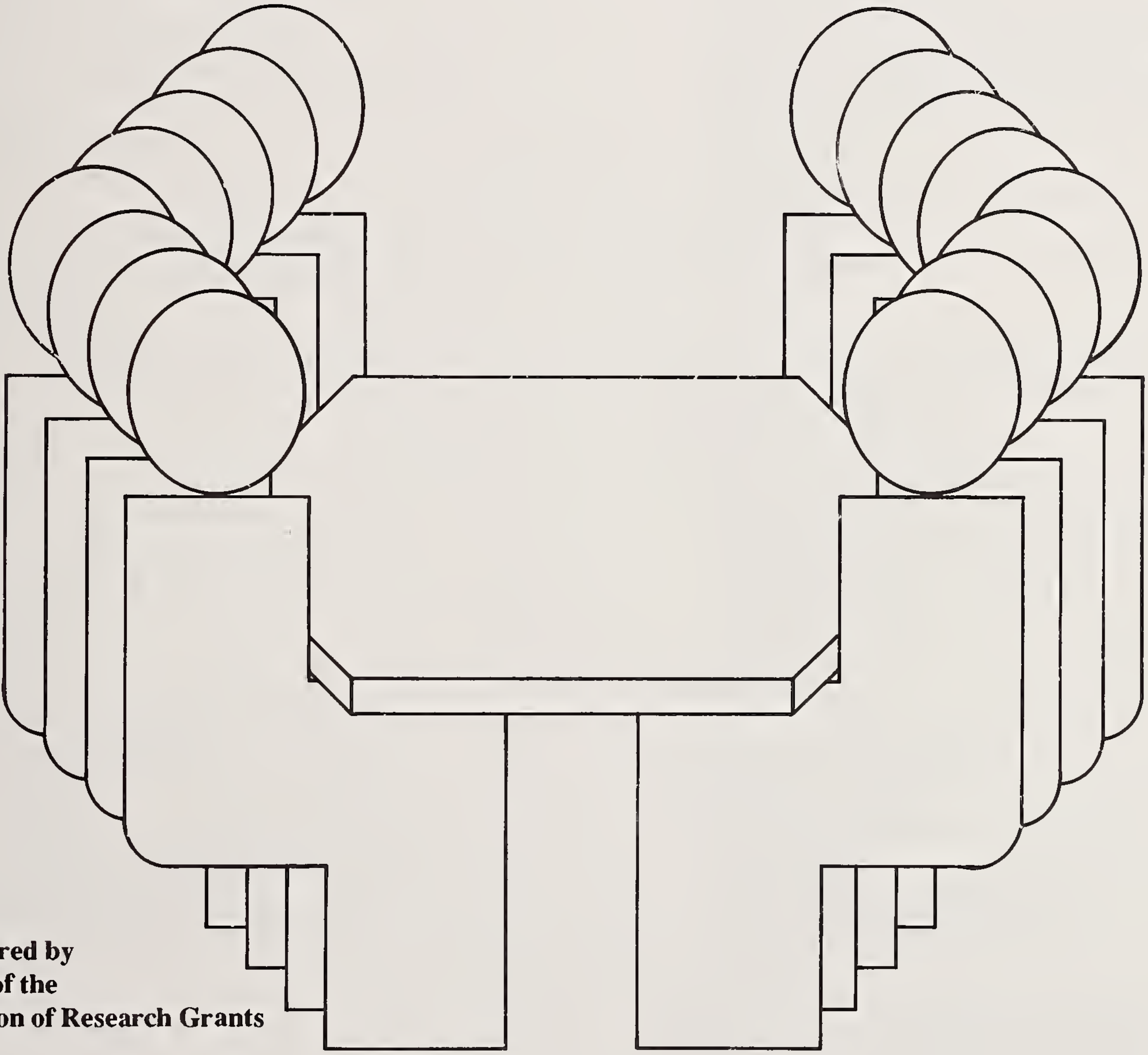

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U.S. Department of Health and Human Services
Public Health Service
National Institutes of Health

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Abbreviations*

AREA	Academic Research Enhancement Award
DDER	Deputy Director for Extramural Research, NIH
BID	NIH Institute, Division, or Center (Referred to as an ”Institute” in this handbook)
CC**	Clinical Center
DHHS	Department of Health and Human Services
DRG**	Division of Research Grants
DRR**	Division of Research Resources
FIC**	Fogarty International Center
IRG	Initial Review Group (Performs initial scientific merit review of grant applications-- called Study Sections within the DRG)
NCI**	National Cancer Institute
NCNR**	National Center for Nursing Research
NEI**	National Eye Institute
NHLBI**	National Heart, Lung, and Blood Institute
NIA**	National Institute on Aging
NIAID**	National Institute of Allergy and Infectious Diseases
NIAMS**	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NICHD**	National Institute of Child and Human Development
NIDCD**	National Institute of Deafness and Other Communication Disorders
NIDR**	National Institute of Dental Research
NIDDK**	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS**	National Institute of Environmental Health Sciences
NIGMS**	National Institute of General Medical Sciences
NIH	National Institutes of Health
NINDS**	National Institute of Neurological Disorders and Stroke
NLM**	National Library of Medicine
NRSA	National Research Service Award
OD	Office of the Director
OPRR	Office for Protection from Research Risks, OD
ORDA	Office of Recombinant DNA Activities, NIAID
PHS	Public Health Service
RCDA	Research Career Development Award
RFA	Request for Applications (Announcement requesting grant application for a research area)
RFP	Request for Proposals (Announcement requesting contract proposals for a project)
RRB	Referral and Review Branch
SBIR	Small Business Innovation Research Program
SRG	Scientific Review Groups (Performs initial scientific merit review of grant applications and contract proposals--called Initial Review Group when pertaining to grant applications)

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* This list includes abbreviations used in this text as well as those commonly encountered in the review of grant applications and contract proposals.

** The two letter abbreviation used for grant applications and contract proposals can be found in the publication, *Activity Codes, Organizational Codes and Definitions used in Extramural Programs.*

1. Introduction

Mission of the National Institutes of Health

The mission of the National Institutes of Health (NIH) is to improve the health of the people of the United States by increasing our understanding of the process underlying human health and by acquiring new knowledge to help prevent, detect, diagnose, and treat disease.

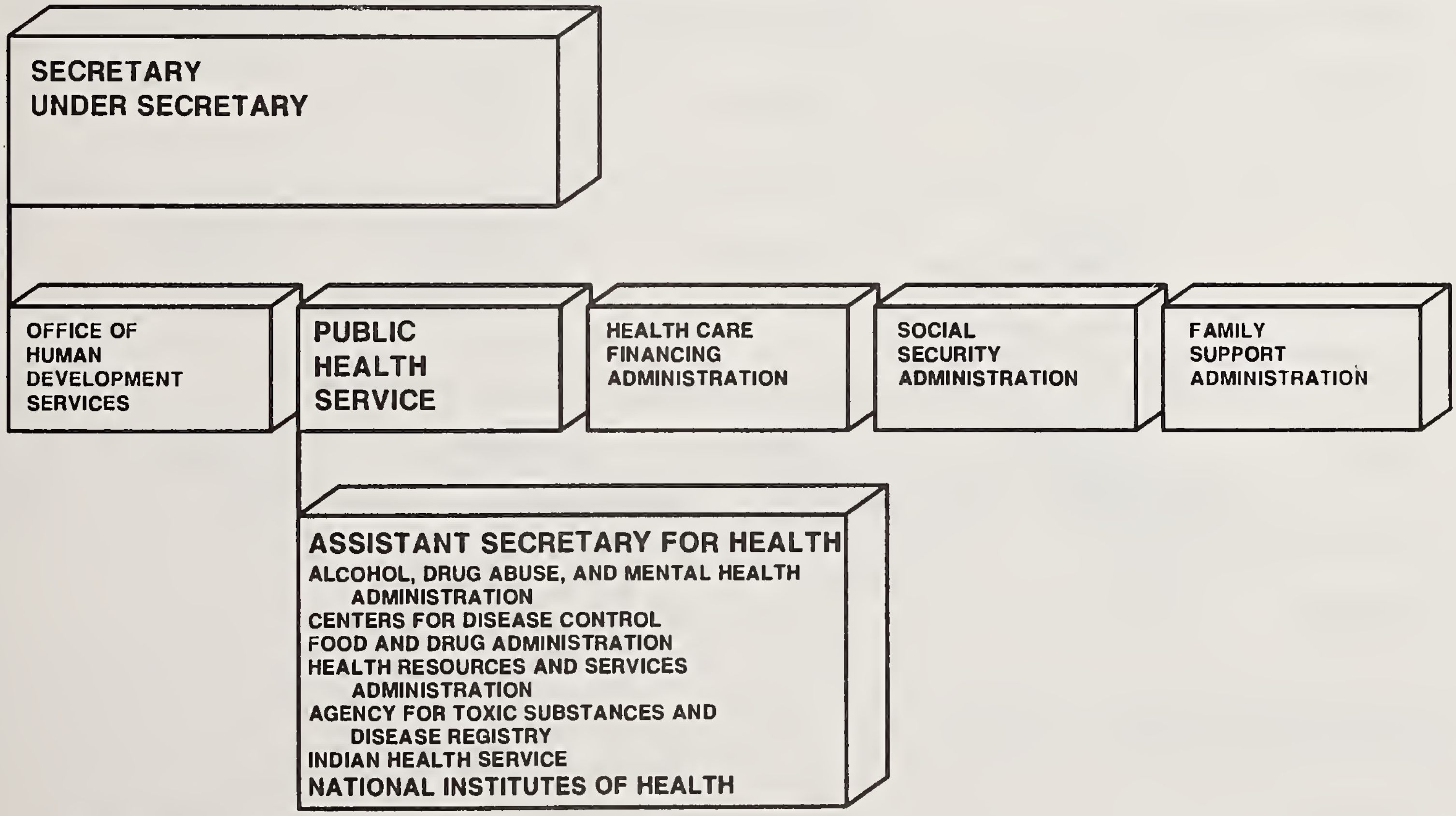
NIH accomplishes this mission by:

- supporting research in universities, medical schools, hospitals, and research institutions in this country and abroad;
- conducting research in its own laboratories and clinics;
- supporting training for promising young researchers;
- helping to develop and maintain research resources;
- identifying research findings that can be applied to the care of patients, and helping to transfer such advances to the health care system;
- promoting effective ways to communicate biomedical information to scientists, health practitioners, and the public; and
- developing and recommending policies related to the conduct and support of biomedical research.

Organization of the NIH

The NIH is comprised of thirteen research Institutes, the Division of Research Resources, two service Divisions, a research hospital called the Clinical Center, the National Library of Medicine, the Fogarty International Center, and the National Center for Nursing Research. While most of the NIH is located in Bethesda, Maryland, the National Institute of Environmental Health Sciences is located in Research Triangle Park, North Carolina, the Intramural program of the National Institute on Aging is located in Baltimore,

Figure 1a.
DEPARTMENT OF HEALTH AND HUMAN SERVICES


SECRETARY
UNDER SECRETARY
OFFICE OF HUMAN DEVELOPMENT SERVICES
PUBLIC HEALTH SERVICE
HEALTH CARE FINANCING ADMINISTRATION
SOCIAL SECURITY ADMINISTRATION
FAMILY SUPPORT ADMINISTRATION
ASSISTANT SECRETARY FOR HEALTH
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
CENTERS FOR DISEASE CONTROL
FOOD AND DRUG ADMINISTRATION
HEALTH RESOURCES AND SERVICES ADMINISTRATION
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
INDIAN HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

Maryland, and some research components of the NIH are located in other areas of the United States. **Figures 1a and 1b** show the general organization of the NIH and its position within the Department of Health and Human Services (DHHS).

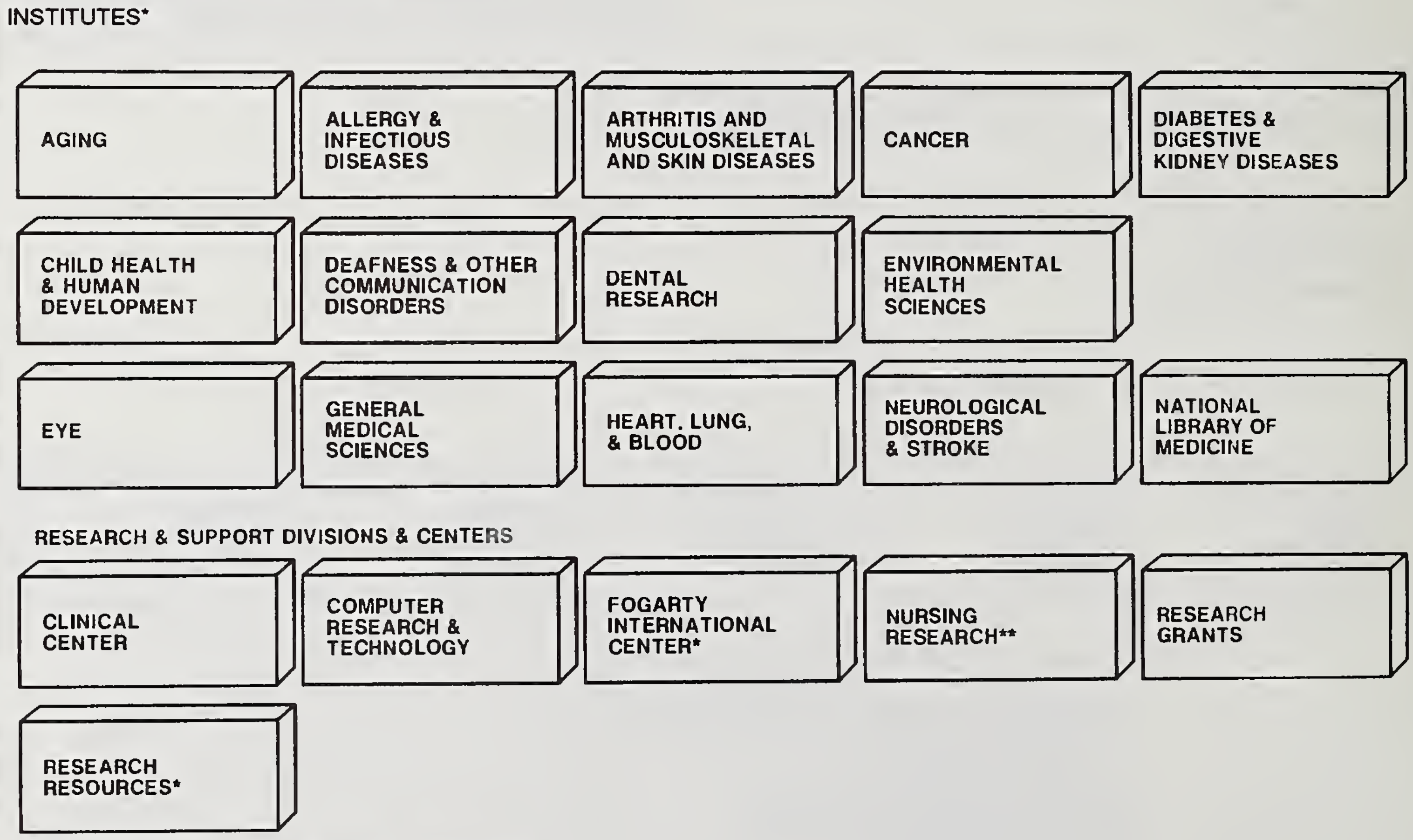
A Typical Institute

Even though there are specific internal variations among the NIH components, all of which are hereafter referred to as "Institutes," a typical organizational pattern exists. Usually, both laboratory and clinical research are conducted directly by an Institute through its intramural program and are supported in other research organizations through an extramural program of grants and contracts (**Figure 2**). An extramural program is organized into specific scientific areas, each of which may provide research funding through grants, contracts, and cooperative agreements.

Extramural Research Support

The diverse mechanisms for extramural research and development are divided into two main categories: grants and contracts. Grants typically support regular research projects, program projects, Academic Research Enhancement Awards, and centers, as well as other forms of assistance such as individual and institutional fellowship awards and various research career awards. In general, the investigator who applies for a grant, through an eligible institution, is responsible for developing the ideas, concepts, methods, and approach for a research project. In contrast, the awarding Institute is responsible for establishing the plans, parameters, and detailed requirements for projects that would be supported by contracts. Contracts are often solicited through requests for proposals (RFPs), while most grants are not solicited. In certain circumstances, however, grant applications are

Figure 1b.
NATIONAL INSTITUTES OF HEALTH


INSTITUTES*
AGING
ALLERGY & INFECTIOUS DISEASES
ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES
CANCER
DIABETES & DIGESTIVE KIDNEY DISEASES
CHILD HEALTH & HUMAN DEVELOPMENT
DEAFNESS & OTHER COMMUNICATION DISORDERS
DENTAL RESEARCH
ENVIRONMENTAL HEALTH SCIENCES
EYE
GENERAL MEDICAL SCIENCES
HEART, LUNG, & BLOOD
NEUROLOGICAL DISORDERS & STROKE
NATIONAL LIBRARY OF MEDICINE
RESEARCH & SUPPORT DIVISIONS & CENTERS
CLINICAL CENTER
COMPUTER RESEARCH & TECHNOLOGY
FOGARTY INTERNATIONAL CENTER*
NURSING RESEARCH**
RESEARCH GRANTS
RESEARCH RESOURCES*

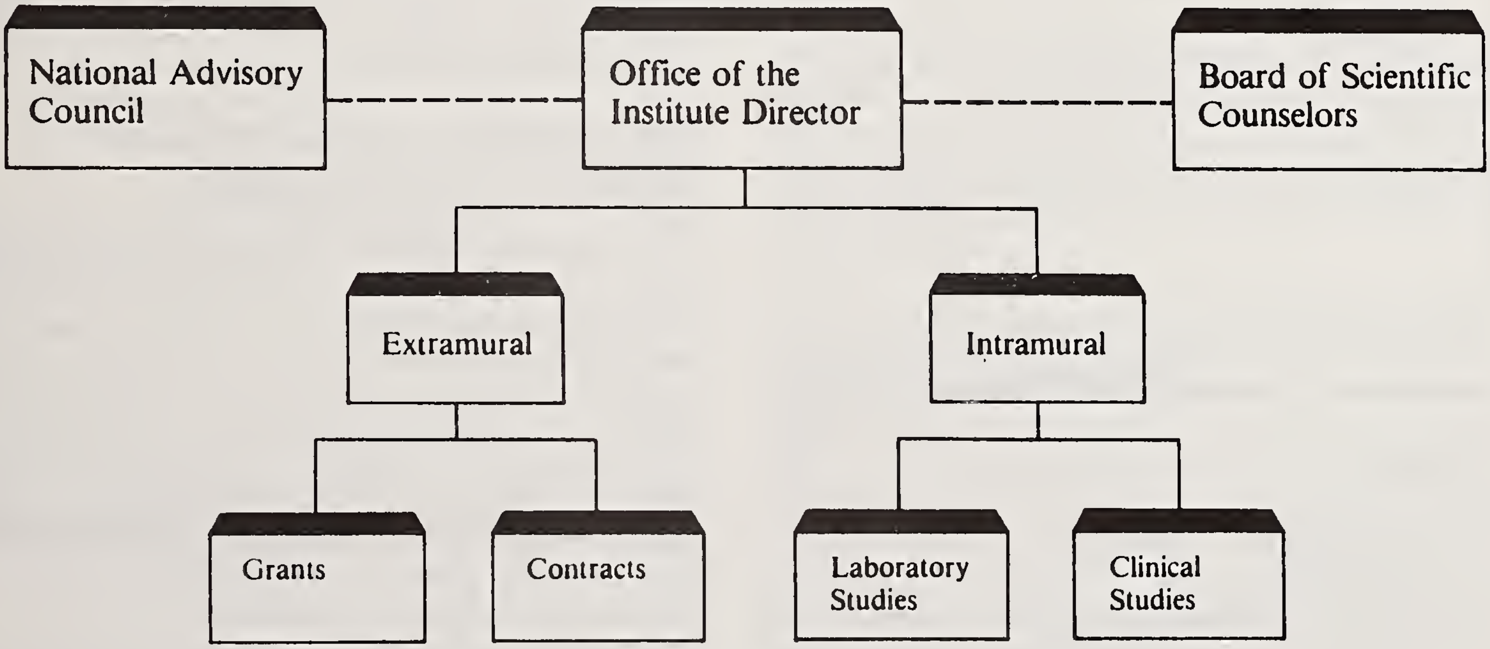
*AWARDS RESEARCH GRANTS AND CONTRACTS
**AWARDS RESEARCH GRANTS

invited to support areas of special interest to an awarding Institute, in which case requests for applications (RFAs) and program announcements (PAs) are issued. RFPs, RFAs, and PAs are published in the *NIH Guide for Grants and Contracts*. Other distinctions between contracts and grants involve such technical issues as the cost reimbursement, the timing of the application or proposal process, the requirements and mechanisms for award and administration, the extent of the involvement of the funding Institute, and the delivery of the end product.

Another form of support is called the cooperative agreement. The cooperative agreement, like the grant, is oriented to support or stimulate the recipient's activities, but provides for substantial involvement on the part of the funding agency during the period of performance. Cooperative agreement awards generally derive from applications responding to RFAs or PAs in which the terms and conditions of such involvement are spelled out.

Grant applications are classified according to type, such as new, competing continuation (renewal), and supplemental applications, and according to activities, such as regular research projects, conferences, program projects, centers, and fellowships. The classification of a grant application is indicated by an identification numbering system that appears in the upper right-hand corner of the first page of the standard application (Form PHS 398). Each part of the identification number has a distinct function. For example: 1RO1 CA12789-01 means the application is a new (1) research project grant (RO1) application assigned to the National Cancer Institute (CA) with a sequentially serial number (12789) requesting a first year of support (O1). Further information concerning extramural codes can be found in *Activity Codes, Organizational Codes, and Definitions Used in Extramural Programs,* a Division of Research Grants (DRG) publication that is updated annually and available from the executive secretary of a review group. This publication also describes the classification and numbering system for contracts. Contracts are classified according to transaction types, such as new, renewal, and continuation of incrementally funded contracts.

Figure 2.
A TYPICAL INSTITUTE


National Advisory Council
Office of the Institute Director
Board of Scientific Counselors
Extramural
Intramural
Grants
Contracts
Laboratory Studies
Clinical Studies

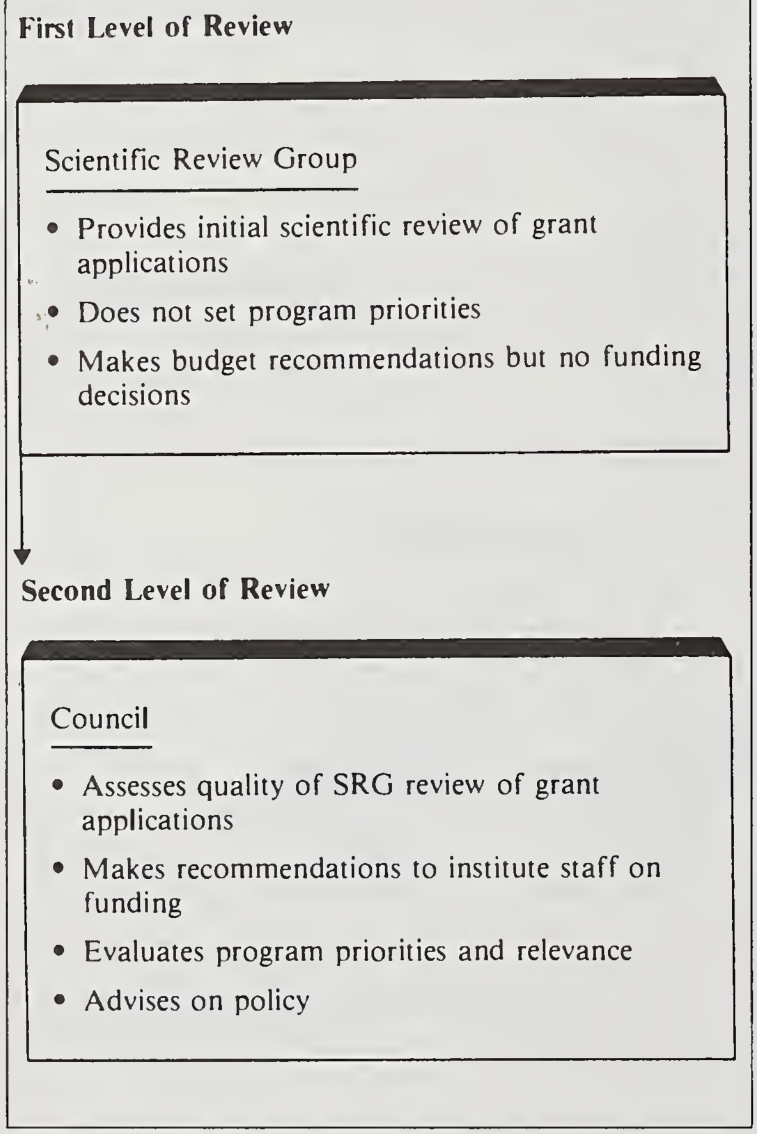
2. The Peer Review System

Because of the magnitude, diversity, and complexity of its research mission, as well as its pursuit of excellence, the NIH draws for assistance on the national pool of scientists actively engaged in research. These scientists assist the NIH by advising on the selection of the most meritorious and the most promising research projects for award.

Dual Review of Grant Applications

The peer review system for grant applications used by the NIH is based on two sequential levels of review, referred to as the "dual review system" (**Figure 3**). The first level involves panels of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. These panels, which are legislatively mandated, are generally referred to as scientific review groups (SRGs) if they review both grant applications and contract proposals, initial review groups (IRGs) if they review only grant applications. In DRG, the panels are usually called study sections.

Figure 3.
THE DUAL REVIEW SYSTEM FOR GRANT APPLICATIONS



First Level of Review

Scientific Review Group

- Provides initial scientific review of grant applications
- Does not set program priorities
- Makes budget recommendations but no funding decisions

Second Level of Review

Council

- Assesses quality of SRG review of grant applications
- Makes recommendations to institute staff on funding
- Evaluates program priorities and relevance
- Advises on policy

The second level of review is by a national advisory board or council, hereafter referred to as a "Council," composed of both scientific and lay representatives who are noted for their expertise, interest, or activity in matters related to the mission of the specific Institute which they serve. Council recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study, as outlined in a grant application, to an Institute's programs and priorities.

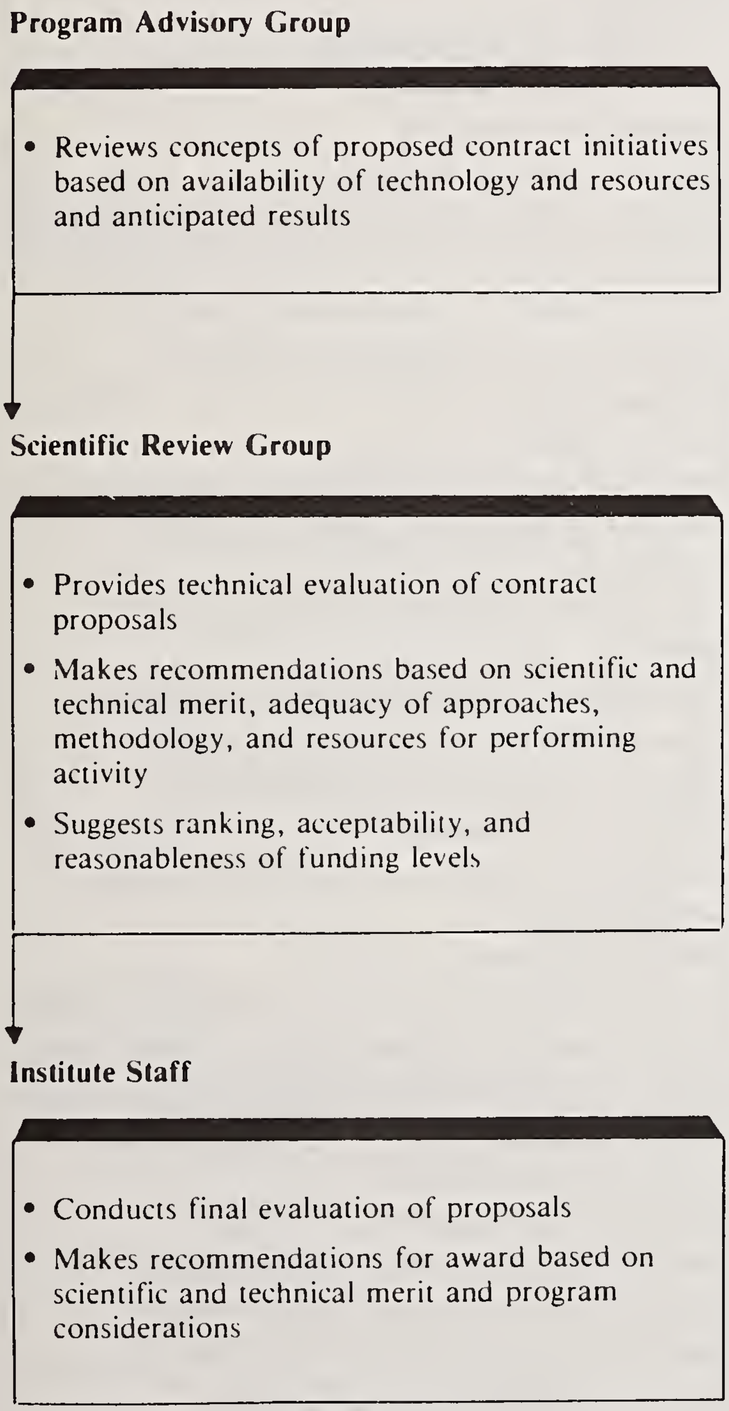
The dual review system, which separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, permits a more objective evaluation than would result from a single level of review. The dual system of review provides the responsible NIH officials with the best available advice about scientific as well as societal values and needs. (The publications listed in **Appendix A** provide more extensive discussions of various aspects of the peer review system used by the NIH.)

Peer Review of Cooperative Agreement Applications

Cooperative agreements are similar to grants in that they are awarded by NIH to assist and support research and related activities. They differ, however, in that grants require minimal involvement of the awarding Institute during the performance of project activities, whereas cooperative agreements give a substantial programmatic (i.e., scientific/technical) role to the Institute. This role may involve cooperation or coordination to assist awardees in carrying out the project, or review and approval of certain processes/phases in the scientific management of the project.

In most circumstances, cooperative agreement applications are accepted and assigned in response to an RFA or program announcement which, by NIH policy, must both specify the nature of Institute staff involvement and describe the review process. Applicants will be advised to describe how they plan to respond to the stated program requirements and criteria, including anticipated staff involvements, and copies of the RFAs and/or program announcements will be sent to all reviewers so that they may better understand the nature of the planned efforts. Consequently, in the peer review process, IRGs will consider applicants' responsiveness to stated requirements and criteria. Otherwise, the peer review process for cooperative agreement applications is the same as that for grant applications such that all subsequent procedural details described herein will apply.

Figure 4.
PEER REVIEW OF CONTRACT PROPOSALS



Program Advisory Group

- Reviews concepts of proposed contract initiatives based on availability of technology and resources and anticipated results

Scientific Review Group

- Provides technical evaluation of contract proposals
- Makes recommendations based on scientific and technical merit, adequacy of approaches, methodology, and resources for performing activity
- Suggests ranking, acceptability, and reasonableness of funding levels

Institute Staff

- Conducts final evaluation of proposals
- Makes recommendations for award based on scientific and technical merit and program considerations

Peer Review of Contract Proposals

The peer review process for contract proposals is similar in principle to that for grant applications (Figure 4). A program advisory group, composed largely of non-Federal advisors, first reviews the contract concept to determine whether the anticipated results will be beneficial to the NIH and whether the necessary technology and resources are available. If the contract concept is approved, a formal solicitation document, the RFP, is prepared and advertised to the scientific community in the *NIH Guide for Grants and Contracts.* The RFP defines the project work requirements and methods and describes the criteria by which subsequent proposals will be evaluated.

Proposals in response to the RFP are reviewed for scientific and technical merit and rated against the announced criteria by an SRG. The final level of review is by senior Institute staff, who review the SRG recommendations and carefully consider the proposals' responsiveness to the RFP, program balance, proposed costs, and availability of funds before making a final recommendation to the Institute Director.

The previous discussion pertains to solicited contract proposals, but Institutes also occasionally make awards in response to unsolicited contract proposals. In this case, the SRG routinely evaluates the concept and the scientific and technical merit at the same session. The final evaluation process is the same as for solicited contract proposals.

How Members of Scientific Review Groups are Selected

The primary requirement for serving on an SRG is demonstrated competence and achievement as an independent investigator in a scientific or clinical discipline or research specialty. Assessment of such competence is based on the quality of research accomplished, publications in refereed scientific journals, and other significant scientific activities, achievements, and honors. Usually, a doctoral degree or its equivalent is required. Service also requires mature judgement, balanced perspective, objectivity, ability to work effectively in a group context, commitment to work assignments, personal integrity to assure the confidentiality of applications and discussions, and the avoidance of real or potential conflicts of interest.

In addition, factors such as geographic distribution and adequate representation of ethnic minority and female scientists must be considered. Further, no more than one member from the same organization may be appointed to any one advisory group. An interval of one year is to occur before a retiring reviewer can be reappointed to the same or another NIH committee, and no one may be appointed to serve simultaneously on two chartered DHHS committees. (Exceptions to these restrictions are rare and must be approved by NIH and DHHS officials).

To identify as many potential reviewers as possible, the NIH invites suggestions for membership on its SRGs and Councils. The executive secretaries, who are NIH health scientist administrators in charge of review and advisory groups, nominate candidates from their own knowledge and experience, recommendations of NIH staff and other scientists, and other sources. Final appointment to SRGs and advisory committees is made by the Director, NIH; appointment to Councils is by the Secretary of DHHS, except for the National Cancer Advisory Board and the President's Cancer Panel, which are made by the President. Appointments are for up to 4 years and staggered so that about a fourth of the membership of a group is new each year.

NIH Reviewers Reserve

The NIH utilizes a centralized NIH Reviewers Reserve (NRR) of consultant reviewers to assist chartered scientific review committees in the peer review of grant and cooperative agreement applications and contract proposals. NRR members serve terms of up to four years and are available to all NIH chartered scientific review committees as reviewers. A NRR member may be asked to serve with a committee whenever there is an identified need for that member's expertise. Therefore, members may serve on a variety of scientific review committees during a four-year appointment.

Responsibilities of the NIH Staff

As shown in **Figure 5**, the review, program, and grants and contract management staff of the NIH have important but separate responsibilities in the review, award, and management processes for grants and contracts.

Figure 5
RESPONSIBILITIES OF NIH STAFF IN THE REVIEW, AWARD, AND MANAGEMENT OF GRANTS AND CONTRACTS

Review Staff

- Nominate SRG members
- Select ad hoc reviewers and site visitors
- Provide orientation for SRG members
- Explain and interpret NIH review policies and procedures
- Assign review responsibilities
- Manage project site visits
- Manage SRG meetings
- Prepare summary statements
- Attend Council meetings to provide requested information in support of committee recommendations
- Communicate with program staff on review
- Discuss review questions with applicants

Program Staff

- Develop program initiatives
- Provide guidance and assistnace to applicants
- Interpret program policy and guidelines for reviewers
- Attend SRG meetings as program resource person(s)
- Provide SRG summary statement to applicants
- Present SRG recommendations to Council
- Discuss review questions with applicants
- Make award decisions
- Participate in identifying prospective SRG and Council nominees
- Evaluate programs
- Communicate with review staff on program matters
- Monitor research progress during the award period

Grants and Contracts Management Staff

- Provide business guidance to applicants and reviewers as necessary
- Participate with program staff in budget negotiations prior to and following awards
- Attend SRG meetings as resource person(s)
- Maintain official grant and contract files
- Assist in developing program policy
- Provide fiscal management of grants and contracts

3. Review Process: Grant Applications

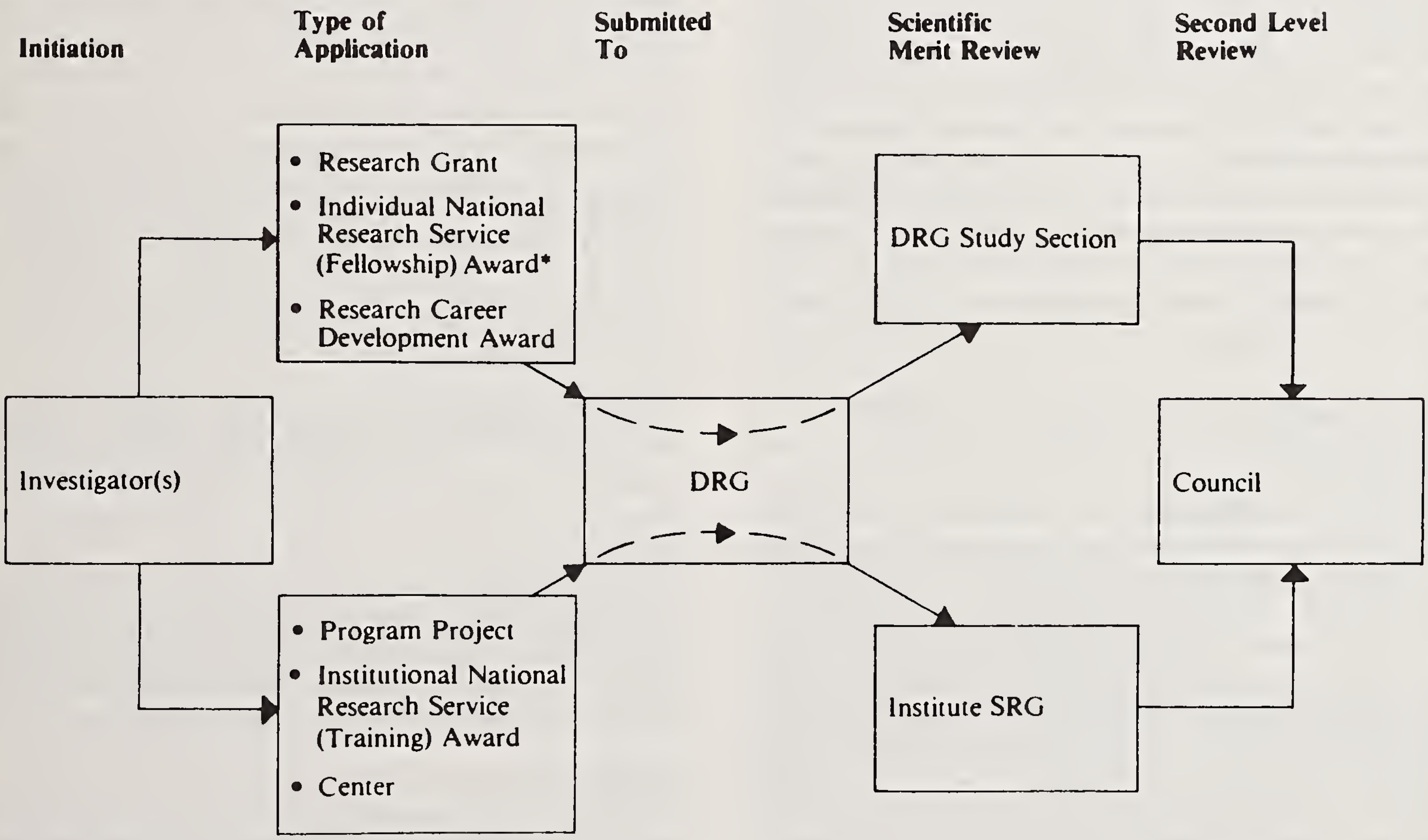
The review cycle for a grant application begins when an investigator submits an application to the NIH, through an institution that qualifies for NIH grants-in-aid, and concludes when the applicant organization and the principal investigator are notified about the recommendation of the Council (Figure 6).

Within the NIH, the review cycle involves the interaction of the DRG and the appropriate awarding Institute. Organizationally, the DRG is accountable to the Director, NIH, and is separate from the Institutes. The DRG has no responsibilities for either the decisions about funding or the management of grant programs.

Assignment of Applications for Review and Institute Funding

Grant applications submitted to the NIH are received centrally in the DRG. In the Referral and Review Branch, referral officers, who are health scientist administrators in the DRG, determine the relevance of each application to the overall mission of the NIH and assign acceptable applications to an appropriate SRG and to an appropriate Institute. Assignment to an SRG is based on the nature of a proposed research project and its conformity to the review responsibilities and

Figure 6.
INITIATION AND REVIEW OF A GRANT APPLICATION



*Does not require council review.

scientific expertise of the membership of the SRG, while assignment to an Institute is based on the Institute's legislatively mandated program responsibility. If the subject matter of an application is pertinent to the program responsibilities of two Institutes, a dual assignment may be made.

Initial Review by Peers

Depending upon the type of research proposed, the first level of scientific merit review is by an SRG located either within the Referral and Review Branch of the DRG Study Section or within an Institute. The study sections in the DRG review most applications for research project grants. The SRGs in the Institutes review program project and center grant applications and other special programs.

The following discussion of the initial review process for the scientific and technical merit of research grant applications contains principles that are common to the review of all grant applications submitted to the NIH. Significant variations in the process for the initial review of some major grant mechanisms, such as research project grants, First Independent Research Support and Transition (FIRST) Awards, program project grants, Academic Research Enhancement Awards, Small Business Innovation Research grants, National Research Service Awards, Support of Scientific Meetings, and Research Career Development Awards are described in subsequent sections.

Reviewers' Preliminary Written Comments

Well in advance of an SRG meeting, the executive secretary sends each member copies of all applications and supporting materials to be reviewed at the meeting. Applications considered to constitute a conflict of interest are omitted from individual mailings. Each member is expected to read and become familiar with these applications. The executive secretary also assigns each application to two or more SRG members for detailed written reviews. Additionally, readers are designated for each application, who are not expected to prepare written reviews, but who are to be especially conversant about those applications. The designated reviewers lead the discussion of their assigned applications at the meeting of the SRG.

If additional information from the applicant is needed, reviewers should inform the executive secretary well in advance of the meeting to decrease chances for a deferral. Reviewers must not contact an applicant directly. All communications with applicants must be handled by the official representative of the granting agency, in this case the executive secretary of the SRG.

For some applications, a reviewer may feel that opinions should be obtained from specially qualified experts who are not members of the SRG. Upon request, the executive secretary will seek mail opinions from other experts. Such requests should be made as promptly as possible so that outside opinions will be received in time for the meeting of the SRG.

Preliminary comments should be sent to the executive secretary's office as early as possible, so that the executive secretary can read all reviews and be aware of any major difficulties or differences of opinion. Moreover, if questions have been raised, the executive secretary can often obtain answers before the meeting.The reviewers' written comments and the subsequent discussions during the review are the basis for the final recommendation of the SRG and for the summary statement prepared by the executive secretary for transmittal to the appropriate Council and to the applicant principal investigator. Consequently, the reviewers' comments should be suitable for their intended uses in format, content, and phrasing. Reviewers must provide specific substantiation of their recommendations of approval, disapproval, or deferral. Unexplained abbreviations and laboratory jargon should be avoided.

The following general guidelines are organized around the standard format for preliminary written reviews. Detailed instructions will be provided by each executive secretary.

Description

Use the abstract on page 2 of the application unless inappropriate, making sure the objectives and procedures are clearly and concisely described. Do not make evaluative statements as part of the description.

Critique

Do not include descriptive information in this section. Provide an analysis of the strengths and weaknesses of the research plan, which consists of Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and an outline of Experimental Design and Methods. (Reviewers must be cognizant of the fact that applicants are instructed to limit their Research Plan to no more than 20 pages.) Descriptive phrases meant to be critical have little or no impact, for the implications are not always apparent to those less familiar with the field. For deferred or revised applications, evaluate changes since the previous review. For competing continuation (renewal) and supplemental applications, evaluate the past performance.

Investigators

Assess the competence of the principal investigator and key personnel to conduct the proposed research. Comments about past performance, training, and/or track record are appropriate and helpful.

Resources and Environment

Evaluate any special attributes or deficiencies relevant to the conduct of the proposed studies.

Budget

Evaluate the direct costs only. Determine whether all items of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support. For supplemental applications, comment on the requested budget in relation to the parent grant.

Other Considerations

Overlap. Identify any apparent scientific or budgetary overlap with active, pending, or planned support.

Misconduct. Identify areas of the application that might indicate the possibility of scientific misconduct (e.g., plagiarism). In some cases, reviewers' concerns arising from these considerations may be sufficient to cause a deferral of the application until clarification is obtained from the principal investigator.

Foreign. Comment on any special talents, resources, populations, or environmental conditions that are not available in the United States or that augment existing United States resources. Indicate whether similiar research is being done domestically and whether there is a need for such additional research. Uniqueness is not a necessary criterion.

Research Involving Human Subjects. Safeguarding the rights and welfare of human subjects involved in research activities supported by DHHS is primarily the responsibility of the institution that receives or is accountable to DHHS for the funds awarded for support of the activity. However, NIH also relies on its SRGs and Councils to evaluate all applications and proposals involving human subjects for compliance with human subject regulations (Code of Federal Regulations, title 45 part 46).

"Human subject' means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. 'Intervention' includes both physical procedures by which data are gathered (for example, venipucture) and manipulations of the subject or the subject's environment that are performed for research purposes. 'Interaction' includes communication or interpersonal contact between investigator and subject. 'Private information' must be individually identifiable, so that the identity of the subject may readily be ascertained by the investigator or associated with the information."

"Research' means a systematic investigation designed to develop or contribute to generalizable knowledge. 'Minimal risk' means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests."

The Department will fund research covered by the regulations only if the institution has filed an appropriate assurance with the NIH Office for Protection from Research Risks (OPRR) and has certified that the research has been approved by an institutional review board (IRB) and is subject to continuing review by the IRB. The IRB Approval Date must be no earlier than one year before the receipt date for which the application is submitted. When research involves only minimal risks and meets certain other conditions, the IRB may waive the requirement for obtaining informed consent. When research is exempt from regulations, as provided under 45 CFR 46.101(b), adherence to ethical standards and pertinent laws is still required. The initial review is expected to reflect the collective standards of the professions represented within the SRG membership.

Exemptions Claimed: Express any comments or concerns about the appropriateness of the exemption(s) claimed.

No Exemptions Claimed: Express any comments or concerns about the appropriateness of the responses to the six required points in the application kit, especially whether the risks to subjects are reasonable in relation to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

Based on the evaluations of its members, the SRG may:

- recommend approval of the activity without restrictions;
- recommend approval of the activity, but record expressions of concern to be communicated to the institution and the principal investigator;
- recommend limitations on the work proposed, the imposition of restrictions, or the elimination of objectionable procedures involving human subjects;
- recommend disapproval of the application if the research risks are sufficiently serious and protection against the risks so inadequate as to consider the entire application unacceptable; or
- recommend deferral for resolution of SRG concerns for human subjects protection.

Concerns which SRG members may wish to express about the adequacy of the protections afforded human subjects used in the project should have "Human Subjects" as a Special Note and a human subjects paragraph explaining the concerns after the "Critique." No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH. Specific concerns and policy interpretation requests may be addressed to the Office for Protection from Research Risks which is responsible for the administration and interpretation of DHHS policy and regulations for the protection of human subjects of research.

The materials listed in Appendix B may be useful guides in evaluating proposals involving human subjects.

Vertebrate Animals . Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH relies on its staff, SRGs, and Councils to review research activities for compliance with the PHS policy for the care and use of vertebrate animals. The care and use of vertebrate animals in funded projects must conform to applicable law and PHS policy. A verification of an institutional animal care and use committee (IACUC) review and an institutional assurance are required for applications involving vertebrate animals. IACUC verifications are valid for up to three years.The general intent of the law and policy can be summarized as two broad rules.

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists.
- Animals should not be confined, restrained, transported, cared for, and used in experimental procedures in a manner to inflict any unnecessary discomfort, pain, or injury.

Reference materials listed in Appendix B are important aids to the review of projects involving the use of animals.

SRG members should express any comments or concerns about the appropriateness of the responses to the five required points in the application kit, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research. Concerns which SRG members may wish to express about animals used in the project should have "Animal Welfare" as a Special Note and an Animal Welfare paragraph explaining the concerns after the "Critique." Questions may be directed to the Office for Protection from Research Risks.

With regard to the above policies concerning human subjects protections and animal welfare, no award may be made unless the applicant institution has given the NIH Office for Protection from Research Risks an acceptable assurance of compliance with PHS policy and all concerns or questions raised by the SRG have been resolved to the satisfaction of the NIH.

Hazardous Research Materials and Methods. The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the SRG in identifying potential hazards, for example, inappropriate handling of biohazardous materials, such as oncogenic viruses, recombinant DNA, chemical carcinogens, infectious agents, and radioactive or explosive material.

If applications pose special hazards, they must be identified and any concerns which SRG members may wish to express about the adequacy of safety procedures should have "biohazard" as a Special Note and a biohazard paragraph explaining the concerns after the "Critique."

No awards will be made until all concerns about hazardous conditions have been resolved to the satisfaction of the NIH.

Recruitment of Minorities and Women. Assess the adequacy of the plans in the application for recruitment of underrepresented minorities into NRSA institutional training programs and recruitment of minorities and women as patients or subjects in clinical studies.

Reviewers' Recommendations

Summarize the strengths and weaknesses of the application and provide a recommendation of approval, disapproval, or deferral.

Approval: Based on the relevant review criteria, the application is of sufficient merit to be worthy of support. (The specific review criteria for the major types of grants are described in a later section.) A vote for approval is equivalent to a recommendation that an award be made provided sufficient funds are available. The recommendation can be for the time and amount requested or for an adjusted time and amount. A priority rating is required.

Disapproval: The application is not of sufficient merit to be worthy of support. Disapproval may also be recommended when gravely hazardous or unethical procedures are involved, when no funds can be recommended, such as in the case of a supplement deemed to be unnecessary, or if the SRG determines that the named principal investigator will not be clearly responsible for the scientific and technical direction of the project. No priority rating is required.

Deferral: The SRG cannot make a recommendation for approval or disapproval without additional information. This information may be obtained by telephone, by a project site visit, or by the submission of additional material by the applicant. Deferred applications are not presented to Councils and are usually reviewed again at the next SRG meeting.

Meetings of the Scientific Review Group

SRGs normally meet three times a year for two or three days each time, depending upon the number and types of grant applications to be reviewed. A DRG study section, which is generally responsible for the review of research project grant applications, may review between 75 and 100 applications at each meeting. Each member may therefore be asked to prepare detailed written critiques on a dozen or more applications. An Institute SRG, which is usually responsible for the review of special-purpose, multidisciplinary applications, such as program projects and centers, normally reviews fewer applications at each meeting. The complexity of many of these applications may, however, impose other requirements.

SRG meetings are conducted by the chairperson, who is one of the members, with assistance from the executive secretary. During the meeting, the assigned reviewers lead the discussion of the applications for which they prepared written critiques. In most instances, a consensus is reached by the group and a recommendation of approval, disapproval, or deferral is made by majority vote. Since all members will have received and are expected to have read all the applications before the meeting, they should be prepared to contribute to the discussions and to rate each favorably recommended application on the basis of their own assessments of merit.

Priority Scores

For each favorably recommended application, each member of an SRG individually records a numerical rating that reflects his or her own opinion of the scientific merit of the proposed research relative to the "state of the art." Members are asked to base the numerical rating on an adjectival scale from 1.0, most meritorious (outstanding), to 5.0, the least meritorious (acceptable) rating, with increments of 0.1.

Outstanding	1.0 - 1-5
Excellent	1.5 - 2.0
Good	2.0 - 2.5
Satisfactory	2.5 - 3.0
Adequate	3.0 - 3.5
Fair	3.5 - 4.0
Acceptable	4.0 - 5.0

In rating applications recommended for approval, reviewers should:

- base their opinions strictly on thoughtful and objective considerations of the review criteria, not on emotional or Institute budgetary considerations;
- judge the merit of each proposal independently of other proposals and according to the "state-of-the-art" in the research area; and
- vote according to their own judgement and not discuss their priority ratings with other members.

After the meeting, the executive secretary averages the individual reviewers' ratings for each favorably recommended application and multiplies by 100 to provide a three-digit rating that is the priority score. Priority scores are included in summary statements, which are forwarded to the Institutes for Council review and to the applicant principal investigators.

In addition to the priority score, a percentile rank is displayed on the summary statement of those applications reviewed by the DRG study sections. Percentiles are calculated against a reference base of research grant applications reviewed by a chartered review group at three consecutive meetings. The percentile represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by the particular study section. The percentile rank of priority scores guides the Councils and Institutes in their decisions about which approved applications are funded. Although Councils may not change these scores, they may recommend--usually on the basis of high or low "program relevance"--whether an approved application should be funded. Nevertheless, even when program interests determine financial support for a project, the percentile rank of priority scores usually influences the final decision about funding.

Site Visits

For the review of some applications, information needed to make a recommendation can be gathered only at the proposed research or training site. When such a situation arises, a site visit is planned. Site visits may occur either before the meeting of the SRG, if an assigned reviewer or the executive secretary recognizes the need for additional information that cannot be obtained by mail or telephone, or after a formal deferral action at the meeting of the SRG, if the group is unable to reach a conclusion on the basis of the information available at their meeting. In addition, site visits are often desirable when the application involves complex coordination, as with many applications for program project or center grants, or when the educational and research environment must be assessed, as with many applications for research training grants.

In each case, the executive secretary assembles a team of site visitors who are charged with gathering information on specific aspects of the proposed project and reporting their findings and recommendations to the SRG at its next meeting. For a research project grant application (R01), the site visit team generally includes two or more members of the SRG, the executive secretary, and a member of the Institute staff, and may also include ad hoc consultants who are experts in critical aspects of the proposed work. For more complex grant applications, such as for program project or center grants, a larger site visit team may be needed. During the site visit, the site visitors meet with the principal investigator and any other personnel considered central to the proposal and discuss the areas in question, such as specific procedures, facilities, and administrative arrangements. The report of the site visit team serves as the basis for discussion of the application at the next meeting of the SRG. This discussion is led by the SRG members who attended the site visit.

Occasionally, a "reverse site visit" may be arranged. In this circumstance, the principal investigator and certain key members of the research team come to the meeting of the SRG to provide additional information.

Summary Statements

Immediately after the meeting of the SRG, the executive secretary prepares a summary statement for each application. These summary statements, which are based on a combination of the reviewers' written comments and the discussion by the SRG during the meeting, become the official documents describing the deliberations of the SRG.

Summary statements include the recommendations of the SRG, a recommended budget, and notations of any special points, such as a potentially hazardous experimental procedure. A separate minority critique must also be provided if two or more members of an SRG voted against the majority recommendation. Individual reviewers' written comments and other notes are not retained after the summary statements have been prepared.

Aspects of an application other than scientific or technical merit, which the Executive Secretary or IRG may consider important enough to be brought to the attention of the Institute or Council is prepared as an addendum to the summary statement and is referred to as an Administrative Note

Summary statements have numerous and important uses.

- Council members use summary statements as the main source of information about applications and as the primary basis for their recommendations.
- Institute staff use summary statements as a basis for discussions with Councils and as guides in the future management of the resulting grants.
- After SRG meetings, Institute staff send each principal investigator a copy of the summary

statement with the percentile rank and priority score displayed. The summary statement is therefore important to investigators in reassessing, adjusting, or improving their research projects, as well as in preparing future applications.

- Summary statements, whenever appropriate, can provide background information to SRGs relative to a revised, supplemental, or competing continuation application submitted in the future.

Initial Review of Applications for Major Types of Grants

The previous section described general procedures that apply to the initial review process for scientific and technical merit. There are, however, special considerations for the review of each type of grant application. These specific considerations for some of the major grant mechanisms are described in this section. (Information about these and other forms of support, such as center grants and resource grants, is available from the executive secretary.)

Research Project Grant (R01) Applications

Objective

The objective of the research project grant is to support a discrete, specified project in an area representing the interests and competency of a principal investigator, who is designated by the applicant institution and who may be assisted by or collaborate with other investigators.

Initial Review

Most research project grant applications are reviewed for merit by study sections in the DRG. In some cases, such as applications received in response to a formal solicitation, the DRG may delegate the initial review to a review group organized by the sponsoring Institute.

Review Criteria

The principal criteria for the initial review of applications for research project grants include:

- scientific, technical, or medical significance and originality of the proposed research;
- appropriateness and adequacy of the experimental approach and methods to be used;
- qualifications and experience of the principal investigator and staff in the area of the proposed research;
- reasonable availability of resources necessary to the proposed research;
- reasonableness of the proposed budget and duration in relation to the proposed research; and
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Site Visits

The review of research project grant applications may on rare occasions require a project site visit, usually in response to deferral of the application by the SRG for that purpose.

A project site visit is recommended only when the review group must obtain fnformation that cannot be communicated satisfactorily through correspondence or by telephone. Usually, such information relates to specific details about the scientific aspects of the proposed project; the arrangements for collaboration; the progress during a previous project period; or the departmental or institutional interest, commitment, support, and plans in relation to the personnel and the project. In some cases, the SRG may need to observe an experimental technique or preparation or assess the appropriateness of special equipment and procedures that are essential to the conduct of the proposed research .

The site visit team customarily includes a small number of consultants, the executive secretary in charge of the review, and a representative from the awarding Institute. Members of the SRG are preferred as consultant visitors because they can discuss the visit and answer questions at the next meeting of the SRG. In many cases, the visitors include ad hoc consultants with special competence in some critical aspect of the proposed investigation.

Site visits for the review of research project grant applications seldom last more than a day. The principal activity is a detailed discussion of objectives, methods, and procedures. A report of the site visit provides the basis for arriving at a recommendation at the next meeting of the SRG.

First Independent Research Support and Transition (FIRST) Award (R29) Applications

Objective

The objective of the FIRST award is to provide a sufficient initial period of research support for newly independent biomedical investigators to initiate their own research and demonstrate the merit of their own research ideas. These grants are intended to underwrite the first independent investigative efforts of an individual; to provide a reasonable opportunity to demonstrate creativity, productivity, and further promise; and to help in the transition to traditional types of NIH research project grants.

The applicant principal investigator must be a beginning investigator who is not in training status at the time the award will begin. This award is not intended for mid career transition to other research endeavors. A FIRST award is for a distinct research endeavor and may not be used merely to supplement or broaden an ongoing project at the applicant institution.

FIRST awards are made for a period of 5 years. These awards are not renewable. The total direct costs awarded must not exceed $350,000 for the 5 years, with no more than $100,000 for any one year. Principal investigators must make a truly significant commitment of time and effort, at least 50 percent, to the proposed research project.

Initial Review

The initial merit review of FIRST Award applications is by study sections in the DRG.

Review Criteria

The review criteria for the initial review of FIRST applications are the same as for research project grant (RO1) applications, except that an applicant principal investigator for a FIRST is less likely to be able to submit an application of the same breadth and depth as an experienced investigator. For example, protocols for the fourth and fifth years may not be as specific as seen in most RO1 applications. Assess whether the principal investigator is an independent, beginning investigator with a five year commitment to the proposed research. Also in the evaluation of the qualifications and experience of the applicant principal investigator, the emphasis is on evaluating the individual's background as a guide to future development into a creative, independent investigator. Evaluate the required letters of reference.

Site Visits

The review of FIRST applications occasionally requires a project site visit. The procedures are the same as for RO1 applications.

Program Project Grant (PO1) Applications

Objective

The objective of the program project grant is to support a broadly based, multidisciplinary, often long-term research program that has a well-defined, overall major goal or basic theme. The individual component projects must have scientific merit and the essential elements of unity and interdependence that constitute a system of research activities and projects directed toward the overall goal of the program.

Initial Review

Applications for program project grants are reviewed for scientific and technical merit by SRGs maintained or organized for that purpose by the Institutes. In some cases, the initial review is conducted by special study section in the DRG.

Review Criteria

The initial review for scientific and technical merit emphasizes two major aspects of the program project grant application: each component project and core unit, and the program as an integrated research effort focused on a central theme.

Review of Projects and Core Units. The review criteria include:

- scientific merit of each research project and the relation of the project to the central theme of the overall program;
- technical merit of and justification for each core unit;
- accomplishments and progress of the projects and core units to date for competing continuation (renewal) and supplemenal applications;
- qualifications, experience, and commitment of the investigators responsible for the research projects or core units and their ability to devote adequate time and effort to the program ;
- appropriateness of the budget for the proposed project and core units; and,

- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Review of the program as an Integrated Effort. The review criteria include:

- significance and importance of the research program to the overall goal or theme of the program;
- appropriateness of the central theme of the proposed program as a feasible approach for a cooperative research effort;
- multidisciplinary scope of the program and the coordination and interrelation of the research projects and core units;
- leadership and scientific stature of the program director and the commitment and ability to devote adequate time and effort to the program;
- participation of an effective number of responsible, experienced investigators;
- academic and physical environment in which the research would be conducted, including the availability of space, equipment, patients, and the potential for interaction with scientists from other departments and other institutions;
- arrangement for internal quality control of ongoing research, the allocation of funds, day-to-day management, internal communication and cooperation between the investigators involved in the program, and contractual agreements;
- presence of an administrative and organizational structure that would facilitate attainment of the proposed objective of the program;
- institutional commitment to the requirements of the program; and
- appropriateness of the budget to the proposed program.

Site Visits

The review of an application for a program project grant often includes a site visit because of the complexity and multidisciplinary characteristics of this type of grant. Program project grant applicants are usually visited before the applications are considered by the SRG.

The initial review for the scientific and technical merit of a program project grant application may be by a review group, which would be formed for that particular purpose and which might also function as the site visiting team, or by a standing committee. In the latter case, the executive secretary would send representatives from the standing committee and additional consultants on the project site visit.

During the site visit, the site visitors meet with the program director, the principal investigators of all the component projects and core units, and the applicant institution's key administrative officials. Site visits for the review of a complex program may require two or three days for the review of all the components of the proposed program.

The results of the site visit are documented in full detail as the summary statement in the case of ad hoc review groups, or in a report in which the site visitors make recommendations to a parent SRG. The SRG uses the information obtained at the site visit in arriving at a recommendation, and the executive secretary usually incorporates the site visit report into the summary statement.

Instructions for the Preparation of Applications

Several of the Institutes have prepared pamphlets to assist potential principal investigators in the preparation of program project applications. These documents, which are available from the Institutes, may be helpful to new SRG members.

Academic Research Enhancement Award (R15) Applications

Objective

The objective of the Academic Research Enhancement Award (AREA) is to stimulate research in educational institutions which provide the baccalaureate training for a significant number of our nation's research scientists but which historically have not been major participants in NIH programs. The AREA will enable qualified individual scientists to receive support for feasibility studies and other small scale research projects.

Initial Review

The initial merit review of AREA applications is by study sections in the DRG.

Review Criteria

The review criteria for the initial review of AREA applications are the same as for research project grant (RO1) applications, except that AREA applications are requests for support of small scale research projects, including pilot or feasibility studies; therefore preliminary data may not be provided.

Site Visits

The review of AREA applications rarely requires a project site visit. The procedures are the same as for research project grant applications.

Small Business Innovation Research (SBIR) Program (R43) (R44) Applications

Objective

The objective of the SBIR program is to promote technological innovation within the American small business community and thereby create jobs, augment industrial productivity, increase competition, and spur economic growth.

Phase I (R43): is to establish the technical merit and feasibility of proposed R&D efforts that may ultimately lead to commercial products or services, and to determine the quality of performance of the small business awardee organization. Awards normally may not exceed $50,000 (both direct and indirect costs) for a period normally not to exceed 6 months.

Phase II (R44): is to continue the R&D efforts initiated in Phase I which are likely to result in commercial products or services. Funding shall be based on the results of Phase I and the scientific and technical merit of the Phase II applications. Only Phase I awardees are eligible to apply for Phase II funding. Phase II awards normally may not exceed $500,000 (including both direct and indirect costs) for a period normally not to exceed 2 years.

Initial Review

The initial review of SBIR applications is conducted by study sections in the DRG.

Review of Phase I

Since Phase I is to be a technical feasibility study, reviewers should not expect the application to provide data establishing feasibility of the project.

The evaluation criteria for Phase I review are as follows:

(1) Scientific and technical merit of the proposed approach;

(2) Qualifications of the principal investigator, supporting staff, and consultants;

(3) Appropriateness of the budget requested;

(4) Adequacy and suitability of the facilities and research environment.

(5) For administrative use by NIH staff, please comment on the potential of the proposed research for commercial application.

The recommended action and the priority score should be based on an assessment of the scientific and technical merit of the application, but not on commercial potential.

In accordance with the Code of Federal Regulation, Title 42, Part 52, the principal investigator of a research project is "a single individual, designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project." "Consultants" from academia cannot provide the scientific/technical direction for the project unless they are in the employ of the small business more than one-half time.

The 6-month budget should be examined and modified, if necessary. Amounts over the prescribed level will be addressed by Institute staff.

The resources and environment should be assessed as to their adequacy and suitability.

Biohazards should be assessed.

If human subjects are involved, the adequacy of human subject protection should be assessed.

If animals are involved, the adequacy of the care and use of animals should be assessed.

The authenticity and structure of the small business, the relationship of the key personnel to the small business and to other institutions, etc., are administrative matters. Comments will be appropriate in Administrative Notes, but these factors will not affect the scientific and technical merit evaluation.

Review of Phase II

The evaluation criteria for Phase II review are as follows:

(1) Degree to which the Phase I objectives were met and feasibility demonstrated.

(2) Scientific, technical, and /or public health importance of the problem or opportunity and anticipated benefits if Phase II research is successful.

(3) The adequacy of the Phase II objectives and methodology for addressing the problem or opportunity.

(4) The technical merit of the proposed research with special emphasis on innovation and/or originality.

(5) The qualifications of the principal investigator, supporting staff, and consultants.

(6) The reasonableness of the budget requested for the work proposed.

(7) The adequacy and suitability of the facilities and research environment.

(8) For administrative use by the NIH staff, please comment on the potential of the proposed research for commercial application.

The recommended action and the priority score will be based on an assessment of the results of the Phase I effort (as reflected in the final report) and the technical merit of the proposed Phase II research. Expectations of Phase I results should take into consideration the brevity of the Phase I grant period (6 months).

The definition of a principal investigator of a Phase II research project is the same as that for a Phase I research project.

The budget should be examined and modified, if necessary. Amounts and term of support over the prescribed level will be addressed by Institute staff.

If a study section believes that a Phase II project can be accomplished within a shorter period of time than proposed by the principal investigator, it may reduce the amount and period of support accordingly.

The resources and environment should be assessed.

Biohazards should be assessed.

If human subjects are involved, the adequacy of human subject protection should be assessed.

If animals are involved, the adequacy of the care and use of animals should be assessed.

The authenticity and structure of the small business, the relationship of the key personnel to the small business and to other institutions are administrative matters. Comments will be appropriate in Administrative Notes, but these factors will not affect the scientific merit evaluation.

NATIONAL RESEARCH SERVICE AWARDS

Postdoctoral Fellowship (F32) Applications

Objective

The objective of the National Research Service Award (NRSA) postdoctoral fellowship is to provide those who hold doctorate degrees with additional research training that will broaden their scientific background and extend their potential for research in specified health-related areas.

Initial Review

The initial review of applications for postdoctoral fellowships is conducted by study sections in the DRG . (The initial review of these applications rarely, if ever, involves a project site visit.)

Review Criteria

The principal criteria for the initial review of applications for postdoctoral fellowships include:

- Candidate's academic background, awards and honors (including professional societies), research experience, professional training, publications, the candidate's references, and research competence and potential;
- quality of the training resources and environment, especially the suitability of the sponsor and department;
- relationship of the additional training to the candidate's background and future objectives;

- strengths and weaknesses of the research proposal, including the training value of the proposal and its relationship to the sponsor's research effort; and,
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Senior Fellowship (F33) Applications

Objective

The objective of the NRSA senior fellowship is to provide opportunities for experienced scientists to make major changes in the direction of their research careers, or to broaden their scientific background by acquiring new research capabilities. These awards will enable individuals beyond the new investigator stage to take time from regular professional responsibilities to receive training to increase their scientific capabilitiies to engage in health-related research. This program is not designed for investigators seeking to prove their research potential. The proposed study must be full-time and must include the conduct of research appropriate to the applicant's background and objective. Support may be requested for a period of up to 2 years.

Initial Review

The initial review of applications for senior fellowships is conducted by study sections in the DRG.

Review Criteria

The principal criteria for the initial review of applications for senior fellowships are the same as for postdoctoral fellowships (F32), except that the emphasis is on the candidate's research competence rather than research potential.

Institutional Training Grant (T32) Applications

Objective

The objective of the NRSA institutional training grant is to enable institutions to provide research training to predoctoral or postdoctoral fellows they select.

Initial Review

The initial review of applications for institutional training grants is conducted by SRGs in the Institutes.

Review Criteria

The principal criteria for the review of an application for an institutional training grant include:

- qualifications, productivity, and research training experience of the participating faculty;
- proposed research training objectives and program design;
- previous training record of the program, including the ability to attract the most promising students and the success such students subsequently achieved;
- institutional commitment to the training program;
- facilities and environment;
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Site Visits

The review of an application for an institutional training grant may include a site visit. The format is adapted to satisfy the review criteria above and usually includes interviews with students as well as with members of the faculty.

Recruitment of Underrepresented Minorities

When reviewing applications for institutional training grants, assess the merit, effectiveness, and adequacy of the applicant program director's plans for recruiting individuals from underrepresented minority groups and the applicant institution's overall efforts to recruit minority individuals. For renewal applications, assess both the plans for minority recruitment and the accomplishments in selecting and training minorities for research positions.

Research Career Development Award (K04) Applications

Objective

The objective of a Research Career Development Award (RCDA) is to foster the further development of scientists who have demonstrated outstanding research potential for independent research careers in the health-related sciences.

Initial Review

The initial review of RCDA applications is conducted by study sections in the DRG.

Review Criteria

The principal criteria for the review of RCDA application include:

- adequacy and appropriateness of the condidate's training;
- significance and originality of the candidate's previous research experience and proposed research;
- candidate's potential for becoming an independent investigator as evidenced by relevant factors, including at least two letters of recommendation;
- institutional commitment to fostering the research career of the candidate, as reflected in the statement of commitment from the sponsoring official, the extent to which the candidate will be relieved of other academic responsibilities to provide additional time for research, and the provision of laboratory facilities and equipment;
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protection against such effects.

Site Visits

The review of an application for an RCDA rarely involves a project site visit the format for which is similar to that for the review of a research project grants (RO1) application.

Support of Scientific Meetings(R13) Applications

Objective

The objective of the Support of Scientific Meetings (conference) grant is to assist in the support of scientific meetings or conferences (either domestic or international) that are directed toward areas of Public Health Service scientific program missions.

Initial Review

The initial review of applications for conference grants may be conducted by SRGs in the Institutes or when requested, by study sections in the DRG.

Review Criteria

The principal criteria for the review of an application for conference grant include:

- the importance of the proposed research conference to workers in the area and to the general biomedical community;
- the timeliness and need for the proposed conference;
- the qualifications of the conference organizers and the proposed participants;
- the adequacy of the scope and content of the proposed conference;
- the appropriateness of the proposed format for achieving the stated goals;
- the adequacy of plans to disseminate the information generated by the conference; and
- the reasonableness of the proposed budget.

Review by National Advisory Councils and Boards

The second level review for grant applications is by Councils of Boards, which assess the quality of the SRG scientific merit reviews, consider the relevance of the proposed research to the Institute's programs and priorities, and advise on Institute policy. Councils can choose not to concur with an SRG approval action based on program or policy considerations or which involves a split vote; they cannot reverse a disapproval action or a unanimous action when their decision is based on scientific and technical merit considerations. When there is disagreement about scientific merit, the application is usually returned for additional review by the same or by a different SRG. If, upon rereview, the SRG recommendation remains the same and the Council still disagrees, the action of the SRG stands.

With the exception of individual fellowship applications and some grant applications recommended at direct costs not exceeding $50,000 annually, grants can not be awarded without recommendations for approval by a Council.

4. Review Process: Contract Proposals

The majority of contract proposals are in response to a published, solicited request for proposals (RFP); unsolicited contract proposals are only rarely accepted by the NIH. For the purpose of this handbook, the following discussion is limited to the review process for a solicited contract project. This contracting process begins with the preparation of an RFP and concludes with the Institute awarding contracts to one or more offerors (Figure 7).

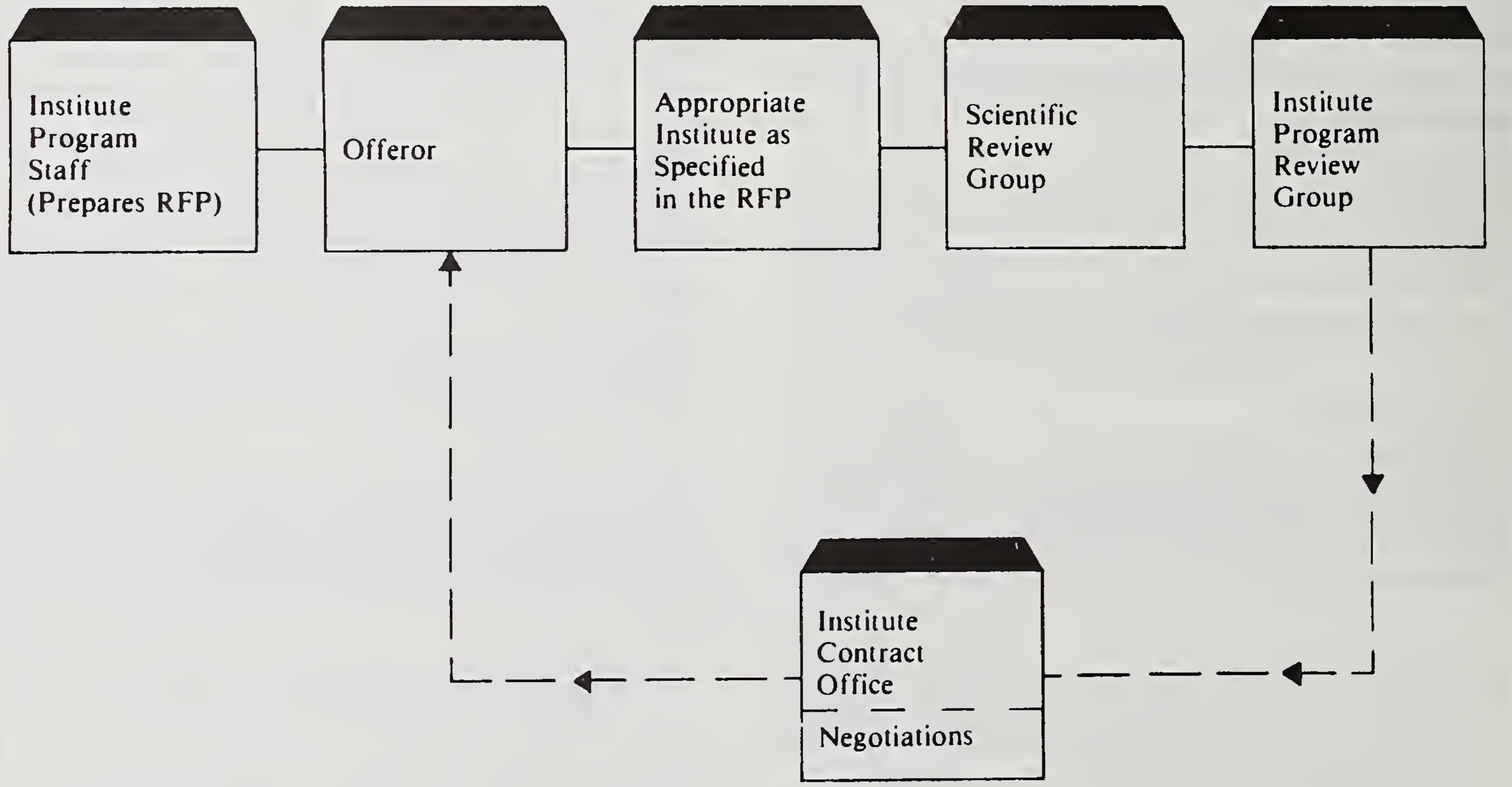
Concept Development and Review

The idea for a contract can come from many sources, such as congressionally mandated directives, Institute staff initiatives, or ideas received from the scientific community. A contract is appropriate when the facilities, staff, or special skills required to procure a specific service or product are not available in the Institute; or when there is a need for a number of institutions to participate in a collaborative project for which the Institute will provide a high degree of guidance. Once Institute staff determine the need for a contract, the concept and technical approach for the proposed project must be reviewed by an Institute peer review group, usually a program advisory committee. An institute may also present the concept for a proposed contract-supported project to the Council for review. A formal solicitation document, the RFP, is then prepared.

Request for Proposals

The RFP specifies the terms, conditions, and provisions for the requested contract. RFP's are announced in the *Commerce Business Daily* as required by law, in the *NIH Guide for Grants and Contracts* as required by policy, in other appropriate publications as determined by program requirements, and in announcements to investigators on Institute mailing lists. Competition is encouraged to the maximum practical extent as required by the laws that govern Federal procurement procedures.

Figure 7.
INITIATION AND REVIEW OF A SOLICITED CONTRACT PROPOSAL


Institute Program Staff (Prepares RFP)
Offeror
Appropriate Institute as Specified in the RFP
Scientific Review Group
Institute Program Review Group
Institute Contract Office
Negotiations

Scientific Review by Peers

An Institute SRG or an ad hoc group is usually responsible for the scientific and technical review of proposals received in response to an RFP.

Reviewers' Preliminary Written Comments

The process for the scientific review of contract proposals is similar to that for grant applications. The executive secretary sends the reviewers copies of all the proposals to be reviewed at the meeting of the SRG. Each member is expected to read the entire set of proposals and to be prepared to participate in the discussion at the meeting. In addition, the executive secretary designates principal or lead reviewers and secondary reviewers for each proposal. These designated reviewers prepare a written evaluation of the contract proposal detailing strengths and weaknesses under each review criteria, and lead the discussion about the proposals during the meeting of the SRG.

Meetings of the Scientific Review Group

The executive secretary of the SRG is in charge of the review meeting, and the project officer and contract specialist are responsible for providing any necessary background information and for answering any questions about the RFP.

Review Criteria

The evaluation criteria for the scientific and technical review of contract proposals are formulated by the Institute to match the specific requirements of the RFP. The review criteria are often weighted. The criteria and weighting factors are usually listed in the RFP and often include such factors as:

- proposer's understanding of the goals and scope of the work solicited;
- proposed method for assuring the timely and acceptable performance of the required work;
- compliance with requirements of the RFP;
- competence of the professional and technical-personnel;
- technical organizaton;
- facilities; and
- where a proposal involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Recommendations and Scores

When the discussion of the proposals has been completed and the strengths and weaknesses of each proposal have been thoroughly examined, the executive secretary requests every member of the SRG to assign each proposal a rating score based on the specific evaluation criteria, and to categorize each proposal as acceptable or unacceptable. These recommendations form the basis for the proposal evaluation report that is transmitted to the Institute program committee for the next level of review.

Site Visits

Occasionally a site visit may be necessary for inspection and evaluation of the proposers' facilities as well as for discussions with scientific and technical staff. Such a visit may be recommended by the SRG or decided upon by the contracting officer.

Summary Reports

After the primary technical review has been compleed, the executive secretary prepares a proposal review summary, which is maintained as a permanent record in the official files. This summary report, which is analogous to that for grant applications, describes the evaluation for each proposal, particulary the strengths and weaknesses for each of the review criteria, and identifies any qualifications that may bear upon the selection of proposals for negotiation and award. The official proposal review summary is forwarded for use by the appropriate Institute program committee in the next level of review.

Program Review

The program review for contract proposals is performed by a committee of senior Institute scientific and contract staff. Their decisions are based on the recommendations of the SRG, subsequent review of revised proposals, program balance, cost, availability of funds, and the proposed means for protecting against any potentially adverse effects upon humans, animals, or the environment.

5. Review-Related Issues

Standards of Conduct

Conflict of Interest

When a member of an SRG or the member's spouse, parent, child, partner, or close professional associate is named in a grant application as the principal investigator, or as an investigator who is currently, or expected to be, responsible for conducting a project, the SRG on which the investigator is a member may not review the application. Instead, the Referral Office, DRG, or the Institute (in the case of an Institute review) arranges to have the application evaluated by another SRG.

Members and reviewers must leave the meeting room when applications submitted by their own organizations are being discussed. In the case of state higher education or other systems with multiple campuses geographically separated, the term "own organization" is intended to mean the entire system where the member or reviewer is an employee, consultant, officer, director or trustee, or has a financial interest. The entire system for a state university normally includes all the campuses and other state institutions which may be part of the same legal entity. However, because of recent rulings, subsystems within 22 States are considered separate organizations or are multicampus institutions where conflict-of-interest prohibitions do not apply for the purposes of the Conflict of Interest Statute. The interest of an employee in a separate campus within those multicampus institutions would be too remote or too inconsequential to affect the integrity of the employee's review of an application from a different campus of that system. See Appendix C for a listing of those institutions considered separate organizations or institutions where conflict-of-interest prohibitions do not apply.

In addition, members and reviewers should be urged to avoid any actions that might give the appearance that a conflict of interest exists. Thus, for example, a consultant should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. Another example might be an application from a scientist with whom the member or reviewer has had long-standing differences which could reasonably be viewed as affecting the consultant's objectivity.

For the review of contract proposals, no one who has submitted a proposal or is from an institution submitting a proposal may participate as a member of the SRG that reviews these proposals.

At the end of a meeting of an SRG, the executive secretary obtains written certification from all consultants that they have been absent from and have not participated in any reviews of proposals or applications where their presence would involve a conflict of interest (Appendix D)

Before appointment to an SRG and annually during the term of service thereafter, each member completes form HEW 474, "Confidential Statement of Employment and Financial Interests." In terms of DHHS standards of conduct and for determining conflict-of-interest situations, members of SRGs are considered 'special government employees.'

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of SRGs must leave all review materials with the executive secretary at the conclusion of the site visit or review meeting.

The protection of the confidentiality of review proceedings is in the best interest of the highly respected peer review system used by the NIH and the NIH tradition of allocating public funds on the basis of research excellence. *Under no circumstances should consultants advise applicants or others of recommendations nor should they discuss the review proceedings outside the review group.* In addition, review group members must not independently solicit opinions or reviews on particular applications or parts thereof from experts outside the initial review group. Members may, however, suggest scientists from whom the executive secretary may subsequently obtain advice.

Confidentiality and the Applicant

There should be no direct communications between members of SRGs and applicants. All communications are handled by the executive secretary of the SRG. Telephone inquiries and correspondence from applicants should be referred to or sent to the executive secretary. Premature advice to the applicant may prove embarrassing to all concerned and be a distinct disservice to the applicant, who may be led into unwise actions on the basis of erroneous information. Premature notification of recommendations to applicants before the review has been completed often leads to misinterpretation and distortion of the discussions of review groups.

Breach of Confidentiality

As is the case with inappropriate disclosure of review proceedings to applicants, any breach of confidentiality--to colleagues, to institution faculty and administrators, or to members of the public--represents an improper intrusion into the privileged nature of the proceedings. Breach of confidentiality ignores the rights of applicants to their proposed work and invades the privacy of fellow consultants serving on review committees and site visit teams. A significant result of such a breach of confidentiality could be to disqualify a current reviewer proven to have broken confidence; to deter qualified consultants from serving on review committees; or to inhibit those who do serve from engaging in free and full discussion of recommendationsat review meetings.

Lobbying

Members of SRGs are asked to bear in mind that when they attend review group meetings they should not discuss their own Government-funded research with Government officials on those days. During this same period, members of SRGs also should not discuss with members of Congress proposed or pending legislation or appropriations that concern the Public Health Service or DHHS.

Privacy Act

Under the Privacy Act, principal investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports, summary statements, and reviewers' written comments, if available. Reviewers' written comments, however, are not retained after their substance has been incorporated into summary statements or site visit reports.

A reviewer may choose whether to sign review comments. If review comments that identify the reviewer have to be made available to a principal investigator, the reviewer will be promptly notified by the Institute or DRG staff.

Open and Closed Portions of Meetings

All Federal advisory committee meetings are open to the public under the provisions of the Federal Advisory Committee Act. All discussions related to the reviews of grant applications and contract proposals, however, are closed to the public under exemptions of the Government in the Sunshine Act (Public Law 94-409).

Consultant Expenses and Reimbursement

Allowable consultant expenses are round trip air transportation, and/or ground transportation, and per diem costs, which can vary according to location. A consultant fee is paid to each participant in an SRG for each day or fraction of a day spent at a site visit or at a meeting of a review group.

Consultants are asked to make their own transportation arrangements and to purchase their own airline tickets. Travel should be by the most direct route. Any additional costs resulting from indirect routing or stopovers should be waived or explained if reimbursement is claimed. When air transportation is used, travelers are expected to use less than first-class accommodations.

Reimbursement forms (Appendix D) will be distributed by the executive secretary before or during the meeting. Reviewers are asked to include Social Security numbers and home addresses to ensure prompt processing and reimbursement of the expenses and fees associated with the trip.

Appendix A. Peer Review Bibliography

Cuca, J. M.: NIH Grant Applications for Clinical Research: Reasons for Poor Ratings or Disapproval, *Clinical Research* 31: 453-461, 1983.

Cuca, J. M., and McLoughlin, W. J.: Why Clinical Research Grant Applications Fare Poorly in Review and How to Recover, *Cancer Investigation: 5(1), 55-58, 1987.*

Eaves, G. N.: Review of Research Grant Applications at the National Institutes of Health, (Updated version (1982) of Who reads your project-grant application to the National Institutes of Health? *Federation Proceedings* 31: 2-9, 1972.)

Eaves, G. N., Rifkin, D. B., Malone, T. E., Ross, R., and Schimke, R. T.: The project-grant application of the National Institutes of Health. *Federation Proceedings* 32: 1541-1550, 1973.

Eaves, G. N.: The grant application: an exercise in scientific writing. *Federation Proceedings* 32: 1541-1543, 1973.

Eaves, G .N.: A successful grant application to the National Institutes of Health: case history. *Grants Magazine* 1: 263-283, 1978

Gordon, S. L.: Ingredients of a Successful Grant Application to the National Institutes of Health. *Journal of Orthopaedic Research* 7: 138-141, 1989.

Gordon, S. L.: Obtaining Grant Funding for Clinical Research. In Fitzgerald, R., Jr. (Ed.): *Non-Cemented Total Hip Arthroplasty* 41: 473-478, 1988.

Merritt, D. H., and Eaves, G. N.: Site visits for the review of grant applications to the National Institutes of Health ; views of an applicant and a scientist administrator. *Federation Proceedings* 34: 131-136, 1975.

Murphy, D. G., and Dean, D. J.: Application and Review Procedures for the NIH Small Business Innovation Research Program, *Institute Insight*, 1-12, March 1984.

Murphy, D. G., and Dean, D. J.: Biomedical Research and Research Training Support by the National Institutes of Health, *Nutrition International* 2: 38-44, 1986.

National Institutes of Health, Report of the NIH Peer Review Committee, December 1988.

Pike J. M., and Bernard, S. C. The research grant budget: preparation and justification in relation to the proposed research. *Grants Magazine* 1:283-286, 1978.

United States, Department of Health, Education, and Welfare, National Institutes of Health, Grants Peer Review Study Team. Grants Peer Review: Report to the Director, NIH Phase I, Volumes I, II, and II,I December 1976, and Phase II, December 1978. (No DHEW publication number.)

United States, Department of Health, Education, and Welfare, National Institutes of Health, Subcommittee on the Survey of the Grant Peer Review System. Survey of the NIH Grant Peer Review System: Analysis of Survey Responses and Comments, July 1, 1977. (No DHEW publication number.)

United States, Department of Health and Human Services, National Institutes of Health, Division of Research Grants. NIH Peer Review Process for Research Grant Applications, 1988. (Videotape).

Appendix B. Bibliography on Research Involving Human Subjects and Animal Welfare

Research Involving Human Subjects

Code of Federal Regulations, Title 45, Part 46, as amended.

Cumulative List of Institutions in General Compliance with HHS Regulations. (Issued periodically by the Office for Protection from Research Risks. or available through WYLBUR, stored on file50, &CUN1DAJ.MPALIST.APRIL88.)

NIH Manual Issuance 4107, Review of Applications and Award of Grants Involving Human Subjects.

NIH Manual Issuance 6000-3-4.55, Contracts Involving Human Subjects

PHS Act, Title IV, Section 474. (42 U.S.C. 2891-3)

PHS Grants Administration Manual Chapter 1-40, Protection of Human Subjects.

Public Law 93-348, Title II, Protection of Human Subjects of Biomedical and Behavioral Research.

(42 U.S.C. 2891-1)

Animal Welfare

Code of Federal Regulations, Title 41, Chapter 3, Subpart 3-4.58, Procurements Involving the Use of Laboratory Animals.

Guide for the Care and Use of Laboratory Animals, DHEW No. (NIH) 78-23 (revised 1985 or succeeding editions).

PHS Grants Administration Manual Chapter 1-43, Animal Welfare.

Public Law 89-544, 1966, amended in 1970, 1976, and 1985.

NOTE: Copies of the above documents are available from your Executive Secretary.

Appendix C. Subsystem Organizations and Multicampus Institutions Considered Separate for the Purposes of Conflict of Interest Stature

The following institutions are considered separate organizations or institutions where conflict-of interest prohibitions do not apply:

ALABAMA; The University of Alabama system, consisting of the University of Alabama, University of Alabama in Birmingham, the University of Alabama in Huntsville, and other Alabama State-owned institutions of higher education.

CALIFORNIA; The University of California campuses, the California Community Colleges, and the California State Universities and Colleges.

COLORADO; The University of Colorado, the system consisting of Colorado State University, the University of Southern Colorado, Fort Lewis College, and other Colorado State-owned institutions of higher education.

CONNECTICUT; The University of connecticut, Connecticut State University, the Connecticut Technical Colleges, and the Connecticut Community Colleges.

ILLINOIS; The University of Illinois, Illinois State University, Western Illinois University, Southern Illinois University, and the Illinois Community Colleges.

INDIANA; The Indiana University system, consisting of eight universities on nine campuses, with the exception of the system-wide schools; the school of Business, the School of Dentistry, the School of Medicine, the school of Dentistry, the School of Medicine, the School of Nursing, and the School of Public and Environmental Affairs, and the other Indiana State-owned Institutions of higher education.

IOWA; The University of Iowa and Iowa State University

KANSAS; The University of Kansas, Kansas State University,Wichita State University, Fort Hays State University, Pittsburgh State University, and the Kansas Technological Institute.

LOUISIANA; Louisiana State University and other Louisiana institutions of higher education.

MASSACHUSETTS; The University of Massachusetts and other Massachusetts State-owned institutions of higher education.

MICHIGAN; The University of Michigan, Michigan State University, and Wayne State University.

MINNESOTA; The University of Minnesota, the Minnesota State University system, and Minnesota Community College System.

MISSOURI; The University of Missouri and other Missouri State-owned institutions of higher education.

NEBRASKA; The University of Nebraska system, consisting of the University of Nebraska-Lincoln, the University of Nebraska at Omaha, the University of Nebraska Medical Center, and other Nebraska State-owned institutions of higher education.

NEW YORK; The campuses of the State University of New York and the City University of New York System

NORTH CAROLINA; The University of North Carolina, North Carolina State, and other North Carolina State-owned institutions of higher education.

OREGON; The Oregon system of higher education, consisting of the University of Oregon, Oregon State University, Oregon Health Sciences University, Portland State University, Western Oregon State College, Southern Oregon State College, Eastern Oregon State College, and Oregon Institute of Technology.

PENNSYLVANIA; Pennsylvania State University, the University of Pittsburgh, Temple University, Lincoln University, and the other State-owned colleges and Universities in Pennsylvania.

TENNESSEE; The campuses of the University of Tennessee.

TEXAS; The separate universities comprising the University of Texas system, Texas A&M system, Texas State University system, East Texas State University, Stephen F. Austin State University, West Texas State University, Midwestern University, University system of South Texas, North Texas State University, Texas Southern University, Texas Woman's University, Lamar University system, Texas Tech University, University of Houston system and Pan American University.

UTAH; The University of Utah and Utah State University.

WISCONSIN; The separate universities comprising the University of Wisconsin system.

Decisions pertaining to other states may be made in the future on a case- by-case basis. State systems other than higher education systems, such as the state bureau of health or elements of the state hospital system, are separate entities not in a conflict-of-interest situation with each other or with the state higher education system.

CERTIFICATION OF NO CONFLICT OF INTEREST

This will certify that in the review of applications conducted by the ____________________ Study Section on ________________________, I absented myself from the room during the review of any application from an organization, institution, or university system where I am an employee, consultant, officer, director or trustee, or have a financial interest. I was not present during the review of any application when my presence would have constituted a real or apparent conflict of interest.

(Signature and Typed Name)	(Signature and Typed Name)
______________________________	______________________________
______________________________	______________________________
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Submit in TRIPLICATE. Please read carefully, including information on reverse.

Department of Health and Human Services
Public Health Service, National Institutes of Health

Claim for Reimbursement of Travel Cost, Per Diem, and Consultant Fee

DATE

NAME OF CHAIRMAN

STUDY SECTION, REVIEW GROUP, OR COMMITTEE

PLACES AND DATES OF ASSIGNMENT

TRAVEL ITINERARY

Note: In cases of combined personal and official business during the same trip, show departure and return time that could have been followed for the sole purpose of this assignment. Take this into account in itemizing expenses below.

LEFT (City, date, hour)

RETURNED (City, date, hour)

DATE OF MEETING(S) OR SITE VISIT(S)

TRAVEL EXPENSES

(A) Cost of transportation (receipts required). If mixed mode of travel, indirect routing or stopovers for personal reasons are involved, claim only cost of usual direct-route round-trip fare. If travel is by privately owned plane, 45¢ an air mile is allowed; or by private auto, ________ ¢ a mile (not to exceed cost by common carrier) will be allowed. Speedometer Readings: **Amount of Advance (when applicable): $**	$
(B) Taxi or limousine used for official business, including up to 15% for tips. (Receipt not required.)	$
(C) Other (Examples - Road and bridge tolls, parking, telegram and telephone calls for official business, conference room rentals.) Receipts required only on items costing $25 or more. Flight or other travel insurance is considered a personal expense and is not reimbursable. Identify claims:	$
(D) TOTAL TRAVEL EXPENSES →	

(E) Lodging: Itemize each day's lodging costs (including tax). This information is needed to determine the appropriate per diem allowance under the Standard Conus system, and the Per Diem Locality Rate method. (See reverse.)

DAY	DATE	LODGING	MEALS AND INCIDENTAL EXPENSES	TOTAL
1st		$	$	$
2nd				
3rd				
4th				
5th				

REMARKS: If unusual circumstances regarding an assignment affect your claim, explain here or on an attached page.

STATEMENT OF PERSONAL SERVICES

I certify that the above itemization reflects costs incurred for official business and that I provided consultant services in connection with this assignment on the dates indicated.

HOME ADDRESS

ADDRESS (where check is to be mailed if other than home)

SOCIAL SECURITY NO.
(See Privacy Act statement on reverse)

NAME (typed)

SIGNATURE OF CONSULTANT

THIS SECTION FOR NIH USE ONLY

1.	I certify that the above Consultant is entitled to a consultant fee for days at $100 per day. Signature of Executive Secretary:	$
2.	Standard Conus $ /Per Diem Locality Rate $	$
3.	Travel (from Item D, above)	$
	ADVANCE DEDUCTED (when applicable)	
4.	TOTAL TO BE PAID →	$

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